



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P207433PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/NL 03/00198	International filing date (day/month/year) 18.03.2003	Priority date (day/month/year) 18.11.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/352		
Applicant GENERAL NUTRITION INVESTMENT COMPANY et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 2 sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 16.06.2004	Date of completion of this report 14.12.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Houyvet, C Telephone No. +49 89 2399-7506 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/NL 03/00198**

I. Basis of the report

- 1 With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-15 as originally filed

Claims, Numbers

1-12 received on 17.11.2004 with letter of 17.11.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☒ the claims, Nos.: 13-15
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-12
	No: Claims	
Inventive step (IS)	Yes: Claims	1-12
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations

see separate sheet

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Re Item V : Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1 : EP-A-0 815 857
- D2 : EP-B-0 829 261
- D3 : WO 01/74345 A
- D4 : WO 99/22728 A
- D5 : FR-A-2 790 645
- D6 : PATENT ABSTRACTS OF JAPAN vol. 1998, no. 01, 30, 1998 & JP 09 227398 A (ZERIA PHARMACEUT CO LTD)
- D7 : US 2001/051160 A1
- D8 : DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; December 1997 (1997-12), DOUCET E. ET AL.; XP002246534, Database accession no. PREV199800081806

Unless otherwise stated, reference is made to the relevant passages cited in the International Search Report for each of these documents.

D1 describes the use of procyanidin, extracted for e.g. from tamarind seeds to treat obesity. The procyanidin of D1 is in a form of a polymer with a degree of polymerisation between 2 and 80. The compositions of D1 are suitable for oral administration and can contain additional plant extracts having antiobesity effects as well as carriers and excipients commonly used in the art (e.g. carboxymethylcellulose, acacia gum, carrageenan).

D2 and D3 both describe oral flavonoid compositions to either promote fat-degradation, suppress appetite, treat obesity, induce weight loss or prevent weight gain. The flavonoids originating in each case from plant extracts (such as tamarind).

D4 also describes the use of flavonoids to treat obesity, and in particular chrysin.

D5 describes an oral nutritional supplement containing polyphenol extracted from grape seeds to treat obesity.

D6 describes an antiobesity agent containing at least one plant selected from grape seed, Pu'er tea or apple among others.

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D7 also describes oral nutritional supplements containing caffeine (in the form of guarana and cola nut) and fibers (guar gum, oat fiber, apple pectin) to control weight. The caffeine acts as a thermogenic fat burning agent and the fibers are used to minimize the tendency to store fat.

D8 also describes caffeine as an energy intake reducer and energy expenditure promoter, while dietary fibers have been shown to increase satiety and fullness.

Thus, none of the prior art documents describes the use of a preparation containing 0.01-250 mg flavonoid and 0.1-100 mg procyanidin to treat or prevent overweight as well as the corresponding nutritional composition. Claims 1-12 are therefore new in view of D1-D8 (Article 33(2) PCT).

Similarly, claims 1-12 involve an inventive step over the cited prior art documents since tests have been filed by the Applicant showing the synergistic effect of chrysin and grape seed on the reduction of appetite in rats (Article 33(3) PCT).